AUG 20 1996

Mr. Paul Williams
4131 N. 34th Street
Arlington, Virginia 22207

Dear Mr. Williams:

This is in response to your FAX to Dr. Elizabeth Yetley at the Food and Drug Administration (FDA) on August 8, 1996, which requested guidelines on claims that can be made for an herbal lozenge. Before we address your specific question, we think it would be helpful to explain how dietary supplements are regulated.

Dietary supplements are regulated under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA), and under the Fair Packaging and Labeling Act. We have enclosed a copy of the DSHEA for your information. The DSHEA defined a dietary supplement. The definition of a "dietary supplement" is found in section 201(ff) of the act. This section states, in part, that the term "dietary supplement" means a product that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form.

If the herbal lozenge is intended to be absorbed from, or to have its effect in the mouth, it is not a dietary supplement under this provision of the act since it is not "ingested." The term "ingestion" has been addressed by the court in United Stated v.Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 393, (E.D.N.Y.) aff'd, 72 F.3d 285 (2d Cir. 1995) which states:

> The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as 'the introduction of food and drink into the stomach'); Webster's Third New International Dictionary (1976) (defining ingestion as 'the taking of material (as food) into the digestive system.').
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> The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Thus, it appears that the product (i.e., an herbal lozenge) that you are inquiring about is not a dietary supplement because it is not ingested, but will have a localized effect in, or be absorbed from, the mouth and throat.

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Further, the manner in which you plan to represent your product (i.e., to temporarily relieve the symptoms associated with nicotine withdrawal) appears to represent this product for drug use within the meaning of section 201(g) of the act. While dietary supplements generally are subject to the food provisions of the act, any representation that a product is intended for medical or therapeutic use may cause the product to be considered a drug. According to section 201(g) of the act, a drug is defined as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals. Additionally, a product may be subject to regulation as a drug if it makes a claim that it is intended for use as an article (other than food) intended to affect the structure or any function of the body of man (section 201(g)(1)(C) of the act) and the claim is not made in accordance with section 403(r)(6) of the act. A manufacturer who wishes to make claims of this nature for a product must contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, Division of Drug Labeling Compliance, Rm. 166 MPN, HFD-310, 7520 Standish Place, Rockville, Maryland 20855, and the product must be proven to be both safe and effective for its intended use.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
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and Applied Nutrition